

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Bryan et al. PATENT NO. 6,001,130

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FOR: HUMAN SPINAL DISC PROSTHESIS

ATTORNEY DOCKET NO.: 46739/268134

Assistant Commissioner for
Patents
Washington, D.C. 20231

DATE: December 14, 2001

PRELIMINARY AMENDMENT

Sir:

Preliminary to any examination on the merits of the accompanying broadened reissue application, please amend the application as indicated below.

IN THE SPECIFICATION

Please amend the paragraph of the specification at column 1, lines 11-15 to read as follows:

This invention relates generally to human prostheses, and especially to spinal column [vertebral] intervertebral disc prostheses. The invention also relates to surgical procedures for preparing the patient to receive [a vertebral] an intervertebral disc endoprosthesis, and for implanting that endoprosthesis in the patient's spine.

Please amend the paragraphs of the specification at column 2, lines 19-27 to read as follows:

It is the primary aim of the present invention to provide [a vertebral] an intervertebral disc endoprosthesis which will perform effectively and efficiently within a patient's spine over a long period of time, and which will not encourage degeneration of or cause damage to adjacent natural disc parts.

It is a related objective to provide a new [vertebral] intervertebral disc endoprosthesis surgical procedure which will decrease post-operative recovery time and inhibit post-operative disc, vertebral body and spinal joint degeneration.

Please amend the paragraph of the specification at column 2, lines 37-39 as follows:

Still another object is to provide [a vertebral] an intervertebral disc endoprosthesis having a resilient element to accommodate shocks and other forces applied to the spine.

Please amend the paragraph of the specification beginning at column 3, line 56 and ending at column 4, line 9 to read as follows:

Turning more specifically to FIGS. 1-3, a portion of a human spine 10 is shown. The illustrated spine 10 has been subjected to a discectomy surgical process. To discourage degeneration of or damage to the natural vertebral bodies 12 and 14 and their respective facet joints, in accordance with the invention, [a vertebral] an intervertebral disc endoprosthesis 18 is affixed between the adjacent natural vertebral bodies 12 and 14. Here this [vertebral] intervertebral disc endoprosthesis 18 comprises a resilient disc body 20 having a relatively stiff annular gasket exterior

portion 22 and a relatively supple nuclear central portion 24. The annular gasket 22 can be formed from a suitable biocompatible elastomer in the range of approximately 70-90 durometer hardness and the nuclear central portion 24 can be formed from a softer biocompatible elastomeric polymer of approximately 30 durometer hardness. In an alternate embodiment, the gasket 22 can extend over and under the nuclear central portion 24 so as to fully enclose it within a thin layer. In a further embodiment, the nuclear central portion, the gasket, and the thin layer extension are molded together to form one piece having different durometer hardnesses.

Please amend the paragraph of the specification beginning at column 7, line 64 and ending at column 8, line 18, as indicated below:

To accurately locate the concaval-convex surfaces in the patient's spine, holes 382A, 384A (FIG. 3) are precisely located and then formed in the bone structure using a measuring instrument centered in the evacuated natural [intravertebral] intervertebral disc space. These holes are then tapped to form female threads therein. When the threads have been formed, the anchors 102, 104 are implanted in the respective tapped holes, thereby creating an imaginary platform of reference points located precisely with respect to the patient's spine. After the holes have been formed and the anchors 102, 104 implanted, a bone surface milling jig (not shown) is affixed to the anchors 102, 104 and the desired concave surfaces of predetermined shape are formed on the inferior and superior surfaces of the opposing vertebral bodies using one of a selection of predetermined milling head or bit sizes. Thereafter, the bone milling jig is removed and the concaval-convex elements 52, 54 identical in shape to the milled surfaces 112, 114 are inserted between the distracted milled vertebral

bodies 12, 14. The distraction device is then moved. The concaval-convex structures are then attached by the same anchors 102, 104 to the bone, thus insuring a precise and stable mate between the bone surfaces and the convex surfaces 52, 54.

IN THE CLAIMS

Please amend the claims as follows.

1. (Amended) [A vertebral] An intervertebral disc endoprosthesis, comprising a resilient body formed of materials varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion; and concaval-convex elements at least partly surrounding the resilient body for retaining said resilient body in a position between the concaval-convex elements, and wherein said concaval-convex elements each comprise generally L-shaped supports, each support having a first concaval-convex leg, the first leg having an outer convex surface for engaging adjacent bone and a corresponding inner concave surface for retaining the resilient body, each support further having a second leg extending generally perpendicularly to the first leg [and adapted for affixation to adjacent bone structure].

2. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 1 wherein said resilient body comprises an annular gasket and a nuclear central portion.

3. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 2 wherein the gasket extends about the nuclear central portion to enclose it within a thin layer.

4. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 3 wherein the gasket, the nuclear central portion, and the thin layer are molded together as one piece.

5. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 1 further comprising cannulated screw means for attaching the concaval-convex element supports to adjacent bone structure.

6. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 5 wherein said cannulated screw means comprises a screw, and a screw anchor seatable within bone structure and adapted to threadably receive the screw.

7. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 6 wherein the screws terminate in the anchor.

8. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 6 wherein the anchor has an open end and the screw proceeds through the open end of the anchor and terminates in the bone of the vertebral body.

9. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 1 further comprising a seal member attached to the concaval-convex elements and surrounding said resilient body.

10. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 9 wherein said seal member comprises a flexible sheet material having a multiplicity of pores, the pores being from about 5 microns to about 60 microns in size.

11. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 10 further including sealing means applied to said flexible sheet material to render said flexible sheet material substantially impervious to the passage of any fluid.

12. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 11 wherein the sealing means is silicone.

13. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 9 wherein said concaval-convex elements and said seal member collectively surround said resilient body with a watertight seal.

14. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 2 wherein said annular gasket is relatively stiff and said nuclear central portion is relatively supple.

15. (Amended) [A vertebral] An intervertebral disc endoprosthesis according to claim 1 wherein at least one of the second legs is hingedly attached to the respective first concaval-convex leg.

16. (Amended) [A vertebral] An intervertebral disc endoprosthesis, comprising a resilient body formed of materials varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion; and concaval-convex elements at least partly surrounding the resilient body between adjacent vertebral bodies for retaining the resilient body between adjacent vertebral bodies in a patient's spine, and wherein said concaval-convex elements each comprise generally L-shaped supports, each support having a first concaval-convex leg, the first leg having an outer convex surface for engaging adjacent bone and a corresponding inner concave surface for retaining the resilient body, each support further having a second leg extending generally perpendicularly to the first leg [and adapted for affixation to adjacent bone structure], wherein at least the second leg is constructed of titanium.

17. (Amended) [A vertebral] An intervertebral disc endoprosthesis comprising a resilient nucleus, first and second rigid concaval-convex elements at least partly surrounding the nucleus, first and second legs formed, respectively, with

the first and second rigid concaval-convex elements, first and second means for affixing the respective legs to vertebral bodies adjacent the concaval-convex elements and nucleus, longitudinal ligament prosthesis means extending between the legs of the first and second concaval-convex elements to inhibit undesirable motion of the vertebral bodies relative to one another, and biodegradable washers positioned between the ligament prosthesis means and the respective legs.

18. (Amended) [A vertebral] An intervertebral disc endoprosthesis comprising a rounded, resilient nucleus body convex on all surfaces and concaval-convex elements, each concaval-convex element being of relatively constant cross-sectional thickness and having an outer convex surface for engaging adjacent bone structure which has been milled to mate with the concaval-convex element outer convex surface, and a corresponding inner concave surface for engaging the rounded resilient body, wherein lubricant is provided between the nucleus body and the concaval-convex elements.

19. (Amended) [A vertebral] An intervertebral endoprosthesis comprising an integral disc unit, said unit including a pair of confronting L-shaped supports having concaval-convex shapes in given legs, a resilient body interposed between the supports, and a flexible seal extending from one support to the other and sealing the resilient body within the supports inside a substantially watertight compartment[, further comprising a plurality of said integral disc units].

20. (Amended) The [vertebral] intervertebral disc endoprosthesis according to claim 19 wherein each support includes a groove about its circumference.

Please add the following new claims.

21. The intervertebral disc endoprosthesis according to claim 19, further comprising a plurality of said integral disc units.

22. The intervertebral disc endoprosthesis according to claim 13, wherein the seal member comprises a flexible sheet secured to each of the concaval-convex elements.

REMARKS

STATUS

This is a broadened reissue application. Upon entry of the present amendment, claims 1-22 will be pending.

SUPPORT

Applicants have amended the specification and claims 1-20 to correct errors and defects as indicated in the accompanying reissue declaration. Additional dependent claims 21 and 22 have been added to provide more complete claim coverage, and are fully supported by the specification and the existing patent claims. No new matter has been added.

Support for the amendment to the specification can be found in the drawings, which clearly indicate that the endoprosthesis is introduced into the intervertebral disc space. Although this would be apparent to anyone of ordinary skill in this art from reading the specification and drawings, the specification has been amended to more accurately reflect this.

Support for the changes to claims 1, 16, and 19 can be found in the specification, *inter alia*, at column 2, lines 19-39 and lines 47-52, and in the drawings as described above with respect to the amendments to the specification, as well as in originally filed claim 17.

Please charge any deficiencies or credit any overpayment in fees to Deposit Order Account No. 11-0855.

Respectfully submitted,



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